April 29, 2026

Asclepion Laser Technologies GmbH
Tom Gruender
RA manager
Contact Address

Re: K261094
Trade/Device Name: YellowStar
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: April 2, 2026
Received: April 2, 2026

Dear Tom Gruender:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tanisha Hithe

Digitally signed by Tanisha Hithe
Date: 2026.04.29 21:27:47 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K261094

Device Name

YellowStar

Indications for Use *(Describe)*

YellowStar is intended for the treatment of benign vascular and benign pigmented lesions

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510 (K) summary K261094

Applicant / Manufacturer Name and Address:	Asclepion Laser Technologies GmbH Bruesseler Strasse 10, 07745 Jena - Germany
510(k) Contact Person:	Mr. Tom Gruender Regulatory Affairs Manager E-Mail: tom.gruender@asclepion.com
Date Prepared:	23 April 2026
Trade Name:	YellowStar
Common Name:	Powered Laser Surgical Instrument
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Main Predicate Device	QuadroStarPRO (K133297), Asclepion Laser Technologies GmbH
Reference Device	V Beam Perfecta (K230990), Candela Corporation

Performance Standards:
There are no mandatory performance standards for this device.

Description of the device:

YellowStar device is equipped with a high-power optically pumped semiconductor laser (HOPSL). It is a class 4 laser product that emits relatively long pulses (> 2 ms) up to continuous emission. A frequency doubling crystal (SHG) generates 577nm at a maximum output power of 8W. The device can operate with either a focusing handpiece or with a scanner handpiece. The laser beam is transmitted from the device to the handpieces via a transfer fiber.

YellowStar includes:

- Control system of the high-power diode laser
- User interface, which allows the user to set all relevant parameters
- Handpieces (applicators) and a transfer fiber to apply the laser radiation to the intended target
- Foot switch to trigger laser emission.
- Delivery of radiation by optical fiber

510 (K) summary K261094

Description of the modifications:

The subject device is a modification to previously cleared QuadroStarPRO due to some technical modifications concerning laser emission parameters and the related controlling software and hardware.

The subject device and the predicate device have the differences shown in the table below:

	Main Predicate Device	Subject device
Device name	QuadroStarPRO	YellowStar
510k number	K133297	K261094
Wavelength	532 or 577nm	577 nm
Power max.	8W @ 532nm 5W @ 577nm	8W
Pulse Duration	1 ms to 95 s and CW	2 ms to 150 ms and CW

Additional reference devices were considered in the substantial equivalence discussion, to justify why the differences do not raise any concern about safety and efficacy.

The subject device has the same intended use of the unmodified device. Moreover, the intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

Based on the nature of the changes implemented, the device underwent and successfully passed performance testing and software verifications and validation according to the relevant standards.

Intended Use:

YellowStar is intended for the treatment of benign vascular and benign pigmented lesions

Technological Characteristics Comparison

Specification	Main Predicate device	Additional predicate device	Subject device
Trade/Device Name	QuadroStarPRO	V Beam Perfecta	YellowStar
Submitter	Asclepion Laser Technologies GmbH	Syneron Candela	Asclepion Laser Technologies GmbH
510(k) number	K133297	K230990	-
Wavelength	532 or 577 nm	595 nm	577 nm
Power, max.	8W @ 532 nm 5W @ 577 nm	N/A	8W
Pulse Duration	1 ms to 95 s and CW	0.45 to 40 ms	2 ms to 150 ms and CW
Repetition rate, max	20 Hz	1.5Hz	20 Hz
Spot size	From 0.5mm, to 2.8 mm handpieces Scanner 1mm	1.5 to 15 mm	From 0.5mm to 1.5mm handpieces Scanner 1mm

510 (K) summary K261094

Non clinical Performance Data:

The following performance data were applied in support of the substantial equivalence determination:

- IEC 60601-1:2005 + AMD 1:2012 + AMD 2:2020: Medical electrical equipment – Part 1: General requirements for safety and essential performance
- IEC 60601-1:2005 + AMD 1:2012 + AMD 2:2020: Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62304:2006 + AMD 1:2015: Medical Device Software – Software life cycle processes
- IEC 62366-1:2015 + AMD 1:2020: Medical devices – Application of usability engineering to medical devices
- IEC 60601-2-22:2019: Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- ISO 14971:2019: Medical devices – Application of risk management to medical devices
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

YellowStar passed all the required testing and is manufactured in compliance will all applicable sections of the above-mentioned performance standards.

Biocompatibility:

The biocompatibility of YellowStar is established based on the predicate device.

Comparison with predicate device:

The subject and predicate devices have the same intended use and the same fundamental scientific technology. Any minor difference does not raise concern about safety and effectiveness.

Conclusions

The differences between the subject and predicate device do not raise new types of questions regarding safety and effectiveness, and the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K133297.